GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1148
ANSWERED ON:29.04.2016
Clinical Trials of Drugs and Medical Devices
Chaudhary Shri P.P.;Joshi Shri Chandra Prakash

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the timeline prescribed for processing and granting approvals for clinical trials of drugs and medical devices, especially the life saving indigenous heart valves;

(b) whether it is a fact that there are inordinate delays in granting approvals causing cost overruns to the developers, relocation of Research & Development facilities to other countries and forcing people to resort to expensive imported devices;

(c) if so, the details thereof and the reasons for such delays;

(d) whether the medical device industry is included under 'Make in India' programme; and

(e) if so, the details thereof and if not, the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a): A time line of 180 days has been prescribed by the Central Drugs Standard Control Organization for processing and granting approvals for clinical trials of drugs and medical devices.
(b) & (c): The applications for grant of approval for clinical trials are processed expeditiously and within the prescribed timeline in most cases. However, in a few cases, the prescribed timelines could not be met for various reasons including longer time required for reviewing the submitted data by Subject Expert Committee (and/or Cellular Biology Based Therapeutic Drugs Evaluation Committee), Technical Committee, and the Apex Committee.
(d) & (e): Manufacture of medical devices in the country is an important component of the Action Plan in respect of pharmaceutical sector which is one of the identified sectors under 'Make in India'. In pursuance of this, a series of decisions including identifying suitable locations for Medical Device Parks and formulation of the National Medical Device Policy have been taken.